K04/281

Datascope

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JUN - 7 2004

Attachment D

Datascope Corp.
Cardiac Assist Division
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510(k) SUMMARY

FOR

DATASCOPE'S 7.5Fr. IAB and ACCESSORIES

(Prepared in accordance with 21 CFR Part 807.92)

A. GENERAL INFORMATION

Submitter:	Datascope Corp. Cardiac Assist Division
Address:	15 Law Drive Fairfield, NJ 07004
Contact Person:	JoAnn Taylor Global Regulatory Affairs Specialist
Phone:	973/244-6123
Fax:	973/244-6243
Date:	May 12, 2004

B. DEVICE INFORMATION

Generic Name:	Intra-Aortic Balloon Catheter (IAB)
Trade Name:	Datascope's 7.5Fr. IAB and Accessories
Classification Name:	Intra-Aortic Balloon Catheters (IABs) are classified under 21CFR 870.3535

C. PREDICATE DEVICE INFORMATION

Datascope's 7.5Fr. IAB and Accessories are substantially equivalent to the following marketed devices:

K031569 - Datascope's Blow-Molded 8Fr. IAB, S/E 6/10/03
K013326 - Datascope's Fidelity 8Fr. IAB, S/E 11/02/01
K002365 – Datascope's Reinforced Catheter Introducer Set, S/E 8/25/00

D. DEVICE DESCRIPTION/INTENDED USE

Datascope's 7.5Fr. Intra-aortic Balloon Catheters and Accessories are used for intra-aortic balloon counterpulsation therapy in the aorta, whereby balloon inflation during diastole and deflation during systole increases blood supply to the heart muscle and decreases the work of the left ventricle. This is the **same intended use** as previously cleared for all other Datascope Intra-Aortic Balloon Catheters.

The intra-aortic balloon is placed in the descending aorta just below the subclavian artery and is intended to improve cardiovascular functioning during the following situations:

- Refractory unstable angina
- Impending infarction
- Acute MI
- Refractory ventricular failure
- Complications of acute MI (i.e. Acute MR or VSD, or papillary muscle rupture)
- Cardiogenic shock
- Support for diagnostic, percutaneous revascularization, and interventional procedures.
- Ischemia related intractable ventricular arrhythmias
- Septic shock
- Intraoperative pulsatile flow generation
- Weaning from bypass
- Cardiac support for non-cardiac surgery
- Prophylactic support in preparation for cardiac surgery
- Post surgical myocardial dysfunction/low cardiac output syndrome
- Myocardial contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects

E. TECHNOLOGICAL CHARACTERISTICS

Datascope's 7.5Fr. IABs and Accessories are substantially equivalent to the predicate devices with regard to intended use.

The modification to the Datascope predicate 8Fr. IAB is dimensional only. The dimension of the co-extruded polyurethane blend catheter will be changed from 8Fr. to 7.5Fr. and the polyimide inner lumen dimension will be changed from .030" to .027".

To accommodate the smaller 7.5Fr. IAB catheter, Datascope's predicate 8Fr. Reinforced Catheter Introducer has been modified from 8Fr. to 7.5Fr., and the Stepped Dilator from 5-8Fr. to 4-7.5Fr.

Modifications to the 8Fr. Reinforced Catheter Introducer Set also include a change in the material of the sheath hub and internal tubing, color code the introducer hub and dilator to industry standard (orange for 7Fr.), change the hub cap design from round to square, change dilator/sheath interface from a snap-fit to a lock-fit design, and add an alternate source contract manufacturer. The material changes are all previously FDA cleared materials.

These modifications to the 8Fr. IABs and Accessories have been demonstrated not to affect safety or efficacy of the device.

F. NON-CLINICAL TESTS

The results of in-vitro tests conducted demonstrate that the functionality and performance characteristics of the device are comparable to the currently marketed devices.

G. CLINICAL TESTS

There has been no clinical evaluation of the new device in the U.S.

H. CONCLUSIONS

Based on the information presented in this 510(k) premarket notification, Datascope's 7.5Fr. IAB and Accessories are considered substantially equivalent to Datascope's currently marketed IABs and accessories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Datascope Corp.
c/o Ms. JoAnn Taylor
Global Regulatory Affairs Specialist
15 Law Drive
Fairfield, NJ 07004

Re: K041281
Datascope's 7.5Fr. IAB and Accessories
Regulation Number: 21 CFR 870.3535
Regulation Name: Intra-Aortic Balloon and Control System
Regulatory Class: Class III (three)
Product Code: DSP
Dated: May 12, 2004
Received: May 13, 2004

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041281

Device Name:Datascope's 7.5Fr. Intra-Aortic Balloon Catheters and Accessories

Indications For Use:

Datascope's 7.5Fr. Intra-Aortic Balloon Catheters and Accessories have the following indications for use:

- Refractory unstable angina
- Impending infarction
- Acute MI
- Refractory ventricular failure
- Complications of acute MI (i.e. Acute MR or VSD, or papillary muscle rupture)
- Cardiogenic shock
- Support for diagnostic, percutaneous revascularization, and interventional procedures.
- Ischemia related intractable ventricular arrhythmias
- Septic shock
- Intraoperative pulsatile flow generation
- Weaning from bypass
- Cardiac support for non-cardiac surgery
- Prophylactic support in preparation for cardiac surgery
- Post surgical myocardial dysfunction/low cardiac output syndrome
- Myocardial contusion
- Mechanical bridge to other assist devices
- Cardiac support following correction of anatomical defects

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041281